ADDITIONAL FEE:

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R E M A R K S

The Office Action issued July 9 2007 has been received and its contents have been carefully considered.

The applicant herein wishes to thank the Examiner in charge of this application, James W. Rogers, Ph.D., for the courtesy and cooperation he extended to applicant and applicant's undersigned counsel during the telephone interview kindly granted on October 23, 2007. Prior to this interview, a proposed Amendment was submitted informally to the Examiner by facsimile for the purposes of discussion. Amendments to the claims proposed in this Amendment are identical to those now being made pursuant to this formal Amendment.

Claims 4, 5, 7, 11 and 17 have been canceled and new method claims 21 - 24 added. Of these new claims, only claim 21 is independent.

The remaining two independent claims 1 and 16 have been substantially amended to overcome the informalities noted by the Examiner on pages 2 - 4 of the Office Action. New

independent claim 21 incorporates the amended language used in claims 1 and 16 as well.

The term "Copolymer" has been changed to "copolymer" in claims 1, 2, 3 and 16.

Claims 1 and 16 have been amended to define the graft copolymer using the language found in claim 1 of applicant's prior US Patent No. 5,942,243. This recitation is supported by the specification of this application, for example on page 5, first paragraph, which states that "the complete disclosure [of US Patent No. 5,942,243 is] incorporated herein by reference." It is believed that these amendments overcome the informalities noted on page 3, first paragraph, of the Office Action.

Claims 1 and 16 have also been amended to delete the reference to a "water soluble polymer". The presence or absence of this polymer forms no part of the invention. This amendment is in response to the Examiner's comments on page 3, second paragraph, of the Office Action.

Finally, claims 1 and 16 have been amended to define the carrier(s) as being "one or more hydrophilic water-based carriers" and to further define what is meant by the term "carrier" by incorporating the subject matter of claim 4. Claim 4 has accordingly been canceled. This amendment is in

response to the Examiner's comments on page 4, first paragraph, of the Office Action.

It may be noted that the term "carrier" (and/or "vehicle") is used in the skincare products(cosmetic and dermatological drugs) trade as a liquid or semi-solid medium in which an "active" ingredient is incorporated as a solution or dispersion depending upon its solubility properties. Various forms of such carriers are now part of the above claims. A cursory examination of labels of skincare products, which are available in a pharmacy or a department store, will indicate that the carriers could contain a dozen or more ingredients such as emollients, oils, waxes, surfactants, preservatives, dermatolgically acceptable solvents, antioxidants, etc. This is the context in which the term "carriers" is used and defined in the above claims, which pertain to compositions for treatment of mammalian skin.

Claims 1 and 16, as previously presented, have been rejected as being anticipated by applicant's prior US Patent No. 5,527,271. As this rejection may apply to claims 1 and 16 as presently amended, it is respectfully traversed.

The '271 patent describes the preparation of hydrogel graft copolymer composition-impregnated fabrics (e.g. a

gauze for treatment of wounds). The copolymer-based compositions are prepared by dipping fabric in a solution of the copolymer and other ingredients in (an) organic solvent(s) followed by drying under heat. It well known that solutions of solutes in solvents (e.g. salt or sugar in water) are molecularly homogeneous dispersions.

Among the carriers cited in the present application, *only a solution in an organic solvent* would fit in the above category. The currently amended independent claims clearly specify *water-based dispersions of the copolymer*. Therefore, preparation of water-based dispersions would not be obvious from the cited disclosure of the '271 patent.

The graft copolymer is water-insoluble. Therefore, it cannot form a molecularly homogenous solution in an aqueous medium. The cream, lotion and ointment are macroscopically homogenous and not molecularly homogenous. Hence, the term "dispersion" is used to describe graft copolymer compositions in these carriers.

In general, the term "solution" refers to homogeneity on a molecular scale (thermodynamic miscibility), whereas the term "dispersion" refers to homogeneity on a macroscopic scale. Therefore isolation of the hydrogel composition from

an organic solvent solution, as described in the '271 patent does not anticipate the present invention.

In any case, claims 1 and 16 have been amended to recite the graft copolymer disclosed and claimed in applicants '243 patent so that these claim are now clearly differentiated from the '271 patent.

Claims 1 and 16 have also been rejected as being unpatentable over the '243 patent alone, and the '243 patent in view of the previously cited patent to Morrissey et al. These rejections are also respectfully traversed for the reasons given in applicant's previously filed Declaration, particularly paragraph 7 thereof.

In the Office Action the Examiner indicates that the hydrogel polymer compositions described in the '243 patent are homogeneous. To the contrary, the '243 patent clearly states the polymer to be water-insoluble and water-swellable:

"Thus, when the graft copolymer is placed in an aqueous environment, it absorbs water and swells to an equilibrium volume, but does not dissolve in water. More specifically, the graft copolymer has an equilibrium water content, defined as the percentage by weight of water absorbed, based or the weight of the fully hydrated sample, of greater than 90%, and typically greater than 95%." (Col.5, lines 4-11).

It is common scientific knowledge that the swollen hydrogel is homogeneous but it is discrete and separate from the aqueous environment in which it is placed (e.g. a soft contact lens in water). For this reason no attempt was made in applicant's Declaration to experimentally demonstrate that a mixture of the '243 hydrogel and water was not homogeneous. Its water insolubility and water swellability described above is a clear proof of the fact that it would form a non-homogeneous mixture with water the same way as a soft contact lens/water mixture is not homogeneous. This point is further clarified in the applicant's Declaration, paragraph 7, which is quoted below:

"By experiment I found that all of the compositions disclosed in the '243 patent form a water-insoluble, non-homogeneous fragmented hydrogels when placed in water. Each particle of the graft copolymer becomes one swollen gel without dissolving into water. This behaviour is very similar to that of crosslinked hydrophilic polymers [e.g. crosslinked poly(N-vinyl 2-pyrrolidone) or crosslinked poly(2-hydroxyethyl methacrylate)]. Typically, such fragmented gels cannot be mechanically homogenized to form a homogeneous solution-like composition. Homogenization of the said crosslinked polymers only results in smaller size of the gel fragments." (Emphasis supplied)

On page 7, the Examiner refers to the following passages from the '243 patent:

"For the purpose of this application the active drug delivery vehicle consists essentially of the thermoplastic graft copolymer, by which is meant that although ingredients such as water, water soluble or water swellable polymers, and adjuvants, such as plasticizer, and diluents, such as solvents can be present, other ingredients that substantially and detrimentally alter the basic and novel characteristics of the drug delivery vehicle are absent." (Col. 5, lines 19-22).

"Formulation of the pharmacologically active agent with the other components in accordance with this invention can be simply accomplished by dissolving all the components (for example the graft copolymer, water soluble plasticizer, and optionally compatible water soluble polymer) in a suitable solvent, such as acetone, chloroform, tetrahydrofuran, N,N-dimethylformamide, etc. and then isolating the formulated mixture by evaporating the solvent by heating under vacuum. Alternatively, all the components can be homogeneously mixed in the melt in a conventional processing equipment such as an extruder or a sigma blade mixer." (Col. 6, lines 52-63).

The above paragraphs refer to process of compounding drug and other ingredients (e.g. plasticizers) with the copolymer to fabricate specific delivery system in a suitable homogeneous form. Such compositions are essentially non-aqueous. It is difficult to envision

compounding water based formulations by either evaporation of organic solvent solutions in a vacuum oven or by mixing in a polymer melt. Typical melt temperatures are in excess of 150° C. Water being very volatile, if present, it would quickly evaporate in such a process. It is also obvious that, if the copolymer could be dissolved in water, there would be no need for organic solvents or melt processing to formulate the ingredients with the copolymer.

The claims 1 and 16 pertain to the dispersion of the copolymer, or compositions comprising of the copolymer, in a water-based dermatological carrier. Although the copolymer and/or the compositions, referred to above, may be homogeneous, it cannot be assumed that their dispersion in an aqueous carrier would be homogeneous. Behavior of such compositions in water is dictated by its water-insolubility and therefore it would be expected to form a non-homogenous dispersion of homogeneously hydrated gels in water.

Thus, the claimed invention is not the copolymer per se but it is the unexpectedly formed dispersion comprising the copolymer in a water based carrier, which dispersion has utility in the treatment of mammalian skin.

In conclusion, it is believed that the independent claims 1 and 16, as well as the new independent claim 21

which is identical to claims 1 and 16 in all the relevant respects, are supported by the specification, are clear and definite, and distinguish patentably over the cited prior art.

This application is therefore believed to be in condition for immediate allowance. A formal Notice of Allowance is accordingly respectfully solicited.

Respectfully submitted,

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Date OCTOBER 30,, 2007